



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EL987587391 US

Express Mail Label Number

September 25, 2003

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1614

ADAM ET AL.

Examiner: Z. Fay

APPLICATION NO: 09/619,349

FILED: JULY 19, 2000

FOR: OPHTHALMIC COMPOSITION

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF ANDREA FETZ UNDER 37 CFR § 1.132

Sir:

I, Andrea Fetz, do hereby declare and state as follows:

1. I am a co-inventor named in the above-identified application.
2. Prior to the priority date of the above-identified application, July 23, 1999, and up through the present time, I have done work related to the clinical development of ketotifen fumarate for, *inter alia*, ophthalmic indications such as allergic conjunctivitis.
3. Prior to the priority date of the above-identified application, there were, on information and belief, five countries, including Argentina and Japan, in which an ophthalmic solution of ketotifen fumarate was marketed.
4. The concentration of ketotifen fumarate in all the ophthalmic solutions mentioned in item (3), above, was 0.069%, yielding an effective concentration of ketotifen of 0.05%.

5. Upon information and belief, prior to the priority date of the above-identified application, there was no publicly available data that would have provided a reasonable expectation that a subject suffering from the symptoms of allergic conjunctivitis would have these symptoms alleviated by the administration of an ophthalmic solution with a concentration of ketotifen fumarate between 0.01 and 0.04%.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willfully false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that willful, false statements may jeopardize the enforceability of the application or patent(s) granted thereon.

Dated: 13. 1. 03

Andrea Fetz
Andrea Fetz